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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/998,250

11/30/2001

Shoukat Dedhar

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05/04/2005

BOZICEVIC, FIELD & FRANCIS LLP

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EXAMINER

WILLIAMS, LEONARD M

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/998,250	Applicant(s) DEDHAR ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

HC

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/08/2005 has been entered.

Examiner notes the amendment to the claims received 09/08/2004 amending claim 1, canceling claims 2-12 and 14. Claim 13 is listed as withdrawn and is not identifiably marked as to being amended on the claim listing though reference is made in the applicants arguments of 09/08/2004. Clarification of the status of claim 13 is required, for the sake of compact prosecution the examiner will address claim 13 on its merits, pending further clarification.

Priority

Examiner notes that the current application is a continuation-in-part (CIP) of 09/390425 now US Patent 6338958 which is a continuation of 09/035706 now US

Patent 6001622 which is a CIP of 08/955841 now US Patent 6013782 which is a CIP of 08/752345 now abandoned which claims benefit to provisional application 60/009074.

The examiner notes that US Patent 6338958 (from application 09/390425) of which the current application is a CIP mentions "small organic molecules" that can inhibit ILK activity in col. 10 lines 5-45. In col. 10 lines 17-26 two specific small molecules are mentioned, wortmannin and LY294002, both of which are clearly stated as agents of interest even though they are inhibitors of PI(3) kinase and not ILK.. No additional small organic molecules are mentioned in US Patent 6338958.

The present application is directed to methods of treating inflammation by administration of ILK inhibitor compounds. On pages 4 and 5 of the current application "small organic compounds" that block ILK catalytic or binding activity either directly or indirectly are said to be described in US Patent 6214813 (which has no common inventors or assignee with the current application) which is incorporated by reference thus admitting it as prior art. Additionally applicant incorporates by reference US Patent 6177273 drawn to antisense inhibitors of ILK and restates that wortmannin and LY294002 are agents of interest. In examples 3 and 4 of the current application the applicant details the use of a small molecule anti-ILK compound called MC-5 in the treatment of an acute mouse ear-swelling edema model of inflammation. Compound MC-5 is not described nor previously mentioned in the present or previous applications. As there is a lack of description of the ILK inhibitor compounds of US Patent 6214813 (incorporated by reference in the current application) and the MC-5 compound in the parent application these compounds receive only the current applications filing date of

11/30/2001 for prior art purposes. Wortmannin and LY294002 are given the filing date of the earlier application 03/05/1998.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 contains the phrase "...specifically inhibits..." the specification does not provide a definition of what "...specifically inhibits..." means nor does the claim contain any clarification as to what the metes and bounds are.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Small Organic Molecule

Claims 1 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the ILK inhibitor compounds of US Patent 6214813, wortmannin, LY294002, and MC-5 does not reasonably provide enablement for "...wherein said ILK inhibitor is a small organic molecule...". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention:

The rejected claims are drawn to "A method for treating chronic inflammation, the method comprising: topically administering an effective amount of an inhibitor of integrin linked kinase (ILK) wherein said ILK inhibitor is a small organic molecule that specifically inhibits ILK activity".

(2) Breadth of the Claims:

The breadth of the claims are exceptionally broad encompassing any "...small organic molecule..." examples could include methane, ethane, ethanol, aspirin, etc...there are no clear structural/functional limitations.

(3) Guidance of the Specification:

The guidance of the specification as to "a small organic molecule" is limited to the ILK inhibitor compounds of US Patent 6214813, wortmannin, LY294002, and MC-5. Though the examiner notes that there is no description as to what MC-5 is, i.e. no chemical name or structure or reference where such information exists.

Compounds possessing other activities are not described in an enabling fashion.

(4) Working Examples:

The applicant provides working examples in example 3 and 4 of the specification for the compound MC-5. The ILK inhibitor compounds of US Patent 6214813 provide examples enabling the particular compounds therein, wortmannin and LY294002 are well known GSK1 inhibitors.

(5) State/predictability of the Art:

The state of the art regarding "a small organic molecule" and its subsequent testing as an inhibitor of ILK or any receptor is high. As the breadth of the term "a small organic molecule" is enormous encompassing a myriad of different structures.

(6) The Quantity of Experimentation Necessary:

The instant claims read on any small molecule. As discussed above, the specification fails to provide sufficient support for agents other than the ILK inhibitor compounds of US Patent 6214813, wortmannin, LY294002, and MC-5. Applicant fails to provide information sufficient to practice the claimed invention, absent undue

experimentation (i.e. experimenting with all small organic compounds). Genetech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Accordingly the claims are evaluated as being drawn to the a method for treating chronic inflammation comprising “a small organic molecule” limited to the ILK inhibitor compounds of US Patent 6214813, wortmannin, LY294002, and MC-5.

Scope of Chronic Inflammation

Claims 1 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of psoriasis, does not reasonably provide enablement for “A method of treating chronic inflammation...”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the

ad; (5) the breadth of the claims', (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The Nature of the Invention:

The rejected claims are drawn to "A method for treating chronic inflammation, the method comprising: topically administering an effective amount of an inhibitor of integrin linked kinase (ILK) wherein said ILK inhibitor is a small organic molecule that specifically inhibits ILK activity".

(2) Breadth of the Claims:

The breadth of the claims are exceptionally broad encompassing all chronic inflammatory conditions. Psoriasis, while considered a chronic inflammatory condition is by no means the only chronic inflammatory condition. Indeed atherosclerosis, arthritis, diabetes, eczema, lupus, etc... are all chronic inflammatory conditions.

(3) Guidance of the Specification:

The guidance of the specification as to "A method for treating chronic inflammation, the method comprising: topically administering an effective amount of an inhibitor of integrin linked kinase (ILK) wherein said ILK inhibitor is a small organic molecule that specifically inhibits ILK activity" while mentioning several additional conditions is enabling only for psoriasis and specifically ILK mediated inflammatory responses related to such.

(4) Working Examples:

The applicant provides working examples in 1-4 involving the characterization of ILK levels in psoriatic skin versus normal skin and that the levels of ILK in psoriatic tissue correlates with the severity of the disease. No other inflammatory conditions are exemplified.

(5) State/predictability of the Art:

The state of the art regarding chronic inflammation and its conditions and causes is high. For a general description of the state of the art the examiner recommends Robbins Pathological Basis of Disease 5th edition chapter 3 and specifically pages 75-84.

(6) The Quantity of Experimentation Necessary:

The instant claims read on all chronic inflammatory conditions but provide disclosure only for psoriasis. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation (i.e. experimenting with all chronic inflammatory conditions). Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Accordingly the claims are evaluated as being drawn to a method of treating the chronic inflammatory disease psoriasis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonjouklian et al. (US Patent 5378725).

Bonjouklian et al. teach, in col. 6 lines 10-60, that wortmannin is an inhibitor of phosphatidylinositol 3-kinase (a kinase involved in mitogenesis, cellular proliferation, and cellular differentiation) useful in the treatment of a variety of PI 3-kinase dependent biological processes including pain, diabetes, inflammation, platelet aggregation, vascular diseases, atherosclerosis (a chronic inflammatory disorder), and restenosis. Bonjouklian et al. teach in col. 7 lines 5-20, that wortmannin can be formulated into pharmaceutical compositions for parenteral, transdermal, rectal, nasal, intravenous or oral administration anticipating the "...method for treating chronic inflammation, the method comprising: topically administering and effective amount of an inhibitor..." of claim 1 and the "...method...wherein said ILK inhibitor is a small organic molecule that blocks ILK catalytic or binding activity" of claim 2.

Claims 1 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Zhang et al. (US Patent No. 6214813).

Zhang et al. teach, in the abstract, pharmaceutical compositions having anti-proliferative activity useful in the treatment of hyperproliferative disorders. Zhang et al. teach, in col. 9 lines 50-65, that the compounds can be administered in a variety of forms including tablets, capsules, ointments, gels, etc. and that the routes of administration include oral, buccal, rectal, parenteral, intraperitoneal, intradermal, transdermal etc.. Zhang et al. teach, in col. 13 lines 1-40 that the compounds can be used to treat hyperproliferative disorders such as psoriasis, arthritis, inflammation, angiogenesis, endometriosis and cancer and that the compounds are integrin-linked kinase inhibitors anticipating the "...method for treating chronic inflammation, the method comprising: topically administering an effective amount of an inhibitor..." of claim 1 and the "...method...wherein said ILK inhibitor is a small organic molecule that blocks ILK catalytic or binding activity" of claim 2.

Conclusion

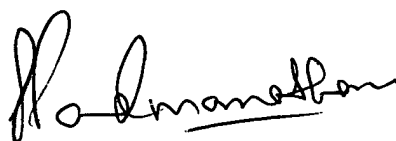
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER